

WHAT IS CLAIMED IS:

1. An oral dosage form, comprising
 - (A) an opioid agonist;
 - (B) acetaminophen, and
 - (C) an opioid antagonist, the ratio of opioid antagonist to opioid agonist to acetaminophen providing a combination product which is analgesically effective when the combination is administered orally, but which is aversive in physically dependent human subjects when administered at the same dose or at a higher dose than the usually prescribed dose of the opioid agonist.
2. The oral dosage form of claim 1, wherein the amount of antagonist included in the oral dosage form causes an aversive experience in a physically dependent addict taking about 2-3 times the usually prescribed dose of the opioid.
3. The oral dosage form of claim 1, wherein the opioid agonist is hydrocodone and the antagonist is naltrexone.
4. The oral dosage form of claim 3, wherein the ratio of naltrexone to hydrocodone is from about 0.03:1 to about 0.27:1.
5. The oral dosage form of claim 3, wherein the ratio of naltrexone to hydrocodone is from about 0.05:1 to about 0.20:1.
6. The oral dosage form of claim 1, wherein the opioid agonist is selected from the group consisting of morphine, hydromorphone, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine, tramadol, pharmaceutically acceptable salts thereof, and mixtures thereof.

7. The oral dosage form of claim 1, further comprising an additional non-opioid drug selected from the group consisting of an NSAID, a COX-2 inhibitor, aspirin, an NMDA receptor antagonist, a drug that blocks a major intracellular consequence of NMDA-receptor activation, dimenhydrinate or a pharmaceutically acceptable salt thereof, an antitussive, an expectorant, a decongestant, an antihistamine and mixtures thereof.

8. The oral dosage form of claim 1, further comprising one or more pharmaceutically acceptable inert excipients.

9. The oral dosage form of claim 6, wherein said opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephephene, cyclazocine, levallorphan, and mixtures thereof.

10. The oral dosage form of claim 6, wherein said opioid antagonist is naltrexone.

11. The oral dosage form of claim 1, further comprising a sustained release carrier causes said opioid agonist to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

12. The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone and said opioid agonist is oxycodone, wherein the ratio of naltrexone to oxycodone is from about 0.037:1 to about 0.296:1.

13. The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone and said opioid agonist is codeine, wherein the ratio of naltrexone to codeine is from about 0.005:1 to about 0.044:1.

14. The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone and said opioid agonist is hydromorphone, wherein the ratio of naltrexone to hydromorphone is from

about 0.148:1 to about 1.185:1.

15. The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone and said opioid agonist is levorphanol, wherein the ratio of naltrexone to levorphanol is from about 0.278:1 to about 2.222:1.

16. The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone and said opioid agonist is meperidine, wherein the ratio of naltrexone to meperidine is from about 0.0037:1 to about 0.0296:1.

17. The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone and said opioid agonist is methadone, wherein the ratio of naltrexone to methadone is from about 0.056:1 to about 0.444:1.

18. The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone and said opioid agonist is morphine, wherein the ratio of naltrexone to morphine is from about 0.018:1 to about 0.148:1.

19. The oral dosage form of claim 11, wherein the sustained release carrier further causes said opioid antagonist to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

20. The oral dosage form of claim 19, wherein the sustained release carrier further causes the acetaminophen to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

21. The oral dosage form of claim 1, wherein the dose of opioid agonist would be subtherapeutic if administered without the acetaminophen.

22. The oral dosage form of claim 1, wherein the dose of acetaminophen would be subtherapeutic if administered without the opioid agonist.

23. The oral dosage form of claim 1, wherein the amount of acetaminophen included in the dosage form is from about 10 mg to about 2000 mg.

24. The oral dosage form of claim 1, wherein the amount of acetaminophen included in the dosage form is from about 25 mg to about 1000 mg.

25. The oral dosage form of claim 1, wherein the amount of acetaminophen included in the dosage form is from about 325 mg to about 1000 mg.

26. The oral dosage form of claim 1, wherein the amount of opioid agonist and the amount of acetaminophen are each lower than would be required when either drug is used alone.

27. The oral dosage form of claim 1, further comprising a sustained release carrier which causes the drugs to be released from the dosage form over a time period from about 8 hours to about 24 hours when the dosage form is orally administered to a human patient.

28. The oral dosage form of claim 27, wherein the opioid agonist is selected from the group consisting of morphine, hydromorphone, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine, tramadol, pharmaceutically acceptable salts thereof, and mixtures thereof.

29. The oral dosage form of claim 28, wherein said opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmefene, cyclazocine, levallorphan, and mixtures thereof.

30. The oral dosage form of claim 29, wherein the amount of acetaminophen included

in the dosage form is from about 10 mg to about 2000 mg.

31. The oral dosage form of claim 27, wherein the amount of either or both the opioid agonist and the acetaminophen are lower than would be required when either drug is used alone.

32. A method of treating pain, comprising administering an oral dosage form which contains an opioid agonist and acetaminophen in amounts which render the dosage form analgesically effective when orally administered, the oral dosage form further including an opioid antagonist in a ratio to said opioid agonist such that the oral dosage form is analgesically effective when administered orally, but is aversive in physically dependent human subjects when administered at the same dose or at a higher dose than the usually prescribed dose of the opioid agonist.

33. The method of claim 32, wherein the amount of antagonist included in the oral dosage form causes an aversive experience in physically dependent addicts taking about 2-3 times the usually prescribed dose of the opioid.

34. The method of claim 32, wherein the opioid agonist is selected from the group consisting of morphine, hydromorphone, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine, tramadol, pharmaceutically acceptable salts thereof, and mixtures thereof and the opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephephene, cyclazocine, levallorphan, and mixtures thereof.

35. The method of claim 34, further comprising preparing said oral dosage form with a sustained release carrier such that the dosage form is administrable on a twice-a-day or on a once-a-day basis.

36. The oral dosage form of claim 32, wherein the amount of acetaminophen included in the dosage form is from about 10 mg to about 2000 mg.